EPISODE 14: TEST TO PROTECT: EQUAL ACCESS TO DIAGNOSTICS FOR ALL

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Garry Aslanyan [00:00:05] Hello and welcome back to our regular followers of the Global Health Matters podcast. I'm very pleased that our listenership keeps growing. For those of you who are joining us for the first time, welcome to the show. I'm your host, Gary Aslanyan. In this episode, we will be exploring the importance of access to diagnostics in global health. Over the past couple of years, diagnostics have moved from laboratories into our living rooms. Many of us have had experience of performing our own COVID tests at home and waiting anxiously to see the results. Unfortunately, to have access to diagnostics is a privilege. Millions of people around the world still lack access to timely diagnosis for a range of diseases. Diagnostics play a critical role in three major global health priorities, such as global health security and antimicrobial resistance and achievement of universal health coverage. In this episode, I'm joined by two guests, each with significant experience and who are driven to reducing the access gaps for diagnostics. Dr Bill Rodriguez is the Chief Executive Officer of FIND, the Global Alliance for Diagnostics. FIND connects health system stakeholders to enhance access to diagnostics. Dr Sikhulile Moyo is a medical virologist and Director of the Botswana Harvard HIV Reference Laboratory. Dr Moyo has also been part of the Botswana Presidential Task Force for COVID-19. Bill and Sikhulile will be highlighting the current inequities in diagnostics, reflecting on the lessons learned from the COVID-19 pandemic and sharing some of the exciting new innovations in the field. Hi, Bill.

Bill Rodriguez [00:02:06] Hi, Garry. How are you?

Garry Aslanyan [00:02:07] Hi, Sikhulile.

Sikhulile Moyo [00:02:08] Hi Garry. How are you?

Garry Aslanyan [00:02:10] Great, thanks. Bill, how has your career journey evolved to focus on diagnostics and what were some of the professional and personal motivators along the way?

Bill Rodriguez [00:02:24] Yeah, thanks, Garry. So I trained in medicine as a clinician, as an infectious disease specialist, and so I see the world as a clinician and with a focus on patient care and how do you help them, the patient in front of you. And so I think probably three different aspects early in my career led me to focus on diagnostic testing. The first is my career coincided with the broad sweep of the AIDS pandemic. As a medical student, I had one 30-minute lecture on HIV. Two years later, in my first role taking care of patients, the first five patients I took care of died of AIDS, and they were all my age in their early twenties. So that was one very formative aspect of my early training in medicine. The second was one of my early mentors was the late Paul Farmer, who sadly passed away recently. And I worked with Paul in Haiti and other places and his influence, the way he demanded equity and said, "we need to take care of every patient the same way we take care of any patients", had a pretty profound influence on me. And then the third was at the time in the late nineties, early 2000, the rapid pace of technology development that I witnessed and the impact of new technologies on high-income diseases like cancer, heart disease, was just overwhelming, and I saw how powerful those technologies could be if we could apply them to global diseases, whether they were infectious diseases or sickle cell disease, or diseases of poverty. And so those three forces, the AIDS pandemic, the influence of Paul Farmer and the rapid development of technologies in the early part of my career, really led me to see the potential for diagnostics to drive equity and clinical care on a global basis.

Garry Aslanyan [00:04:03] Thank you. Sikhulile, what about you? What inspired you to become a virologist and what do you find most satisfying in your job?

Sikhulile Moyo [00:04:15] That's a good one. I started seeing a lot of people dying from HIV, and it was very close to me because I lost some family members. Two brothers and my sister then. And I realized that the pandemic was on us. And you remember, there was no cure at the time, and there was very little hope. And at that time, I met a man who was a virologist and I got interested because of the passion to see how to help. And as a virologist, I realized that looking at new tools of diagnosis for HIV. And that really inspired me, that you can do basic science that translates to so much impact in public health. So that really started my passion for research and also for diagnostics. And I trained under him, and it really gave me a passion to pursue a career in virology. So my passion now is to see timely diagnostics that impact patient outcomes and public health response. That's an intersection of my career and anything that I can do either to promote improvement of access to diagnostics, research that informs public health, that really changes how I look at things.

Garry Aslanyan [00:05:42] So both of you have really reflected on how the inequities in terms of access to diagnostics have impacted various health issues. So Bill, the current pandemic clearly exposes a lot of fragilities when it comes to diagnostic systems. So can you tell our audience what they are, especially in low- and middle-income countries?

Bill Rodriguez [00:06:05] There's a saying that's come up again and again in the past years that pandemics don't create any new problems in society, they just reveal all the existing ones. And I think that's been extremely clear when it comes to testing and diagnostic systems in low- and middle-income countries. In the past 20 years, we've invested heavily in HIV testing. We have centralized laboratories that do high volumes of viral load tests and can turn around tests in 24 hours, we've invested in tuberculosis testing, malaria testing, and we have strong systems there. And selectively in a few other areas like human African trypanosomiasis, or HAT, through a very targeted programme of testing to eliminate that disease. But pandemics, almost by definition, are community based diseases. Whether you're talking about Ebola or SARS-CoV-1 or SARS-CoV-2, they spread person-to-person in communities and that could become pandemics, and we've realized now that we failed to invest in community based testing systems, platforms that can be used as primary health care centres, community health workers as testers, and that failure to invest in a more community based platform instead of a vertical approach, even for HIV, which is a broad disease with impact at the primary health care level, it has revealed that there's a major gap in our ability to respond to pandemics and that's just played out over the past years with COVID. We've really been behind in trying to get testing out to communities through community based testing programmes because we failed to invest in those. And we didn't realize it until COVID really emerged and made it quite clear.

Garry Aslanyan [00:07:44] And Sikhulile, in Botswana, where you work, what are some of the gaps that still exist in bringing the diagnostic capacity to communities?

Sikhulile Moyo [00:07:53] Yeah, that's an important one. I think the systems have grown vertically and when COVID came, it exposed that some models of centralizing care are detrimental to making sure that people access health. Botswana has moved a lot in terms of increasing access to diagnostics, especially in urban areas or peri-urban areas. And some of the gaps are increasing access to very remote areas. And that has been very, very important in making sure that diagnostics are efficient, the timely reporting so that the access that is given at least allows for timely response. And I think, just focusing on infectious diseases alone is also a time bomb probably because of the nature of the funding, focusing on HIV and TB to the detriment of looking at what should we do for NCDs, for example. But in terms our response,

we need to make sure that we close those gaps because the COVID pandemic has really shown us that we need to be ahead of the game in terms of diagnostics. We are used to lab driven testing and properly, maybe nurse-driven testing. But the pandemic quickly showed us that the health system was overwhelmed and there was not enough people to test. You had the testing equipment, but not enough people to do the test. And that really helped us to say, okay, we need to be innovative here. How can we use the community? How can we train lay workers? How can we repurpose lay workers to really run the testing? And that was an opportunity, for example, to expand the testing and really increased testing rates by more than 200-300%, just by repurposing different cadres to increase access to testing. And I think that lesson should be important as a lesson for any pandemic that may come in that we need to reduce complexity in testing.

Garry Aslanyan [00:10:15] Both of you mentioned the fragilities of the systems that have been exposed due to the pandemic and the experience we had with COVID. So Bill, is there any action that has been catalyzed on a global or other level towards equity in diagnostics, both in terms of future pandemic preparedness, but also for all the other health inequity issues that you already both reflected on?

Bill Rodriguez [00:10:44] One thing that we shouldn't under-emphasize is how relevant testing has become in this pandemic. We may not remember all the way back to two years ago, but in the early days of this pandemic, we were acutely aware of how important testing was and how little access we all had to it everywhere in the world. And of course, that's the daily experience of most people to the tests they need in low- and middle-income countries. But even wealthy countries and wealthy people realized, "I can't access a test when I need it." And I think that relevance has persisted for two years. People are very aware of the role of testing in their own health across the globe. Political leaders, Dr Tedros on a daily basis, Heads of State on a weekly basis, from President Biden to President Ramaphosa, are talking about testing to the public. And I think that's really essential because now people understand, hey this is a critical part of our health system and we need to make sure it's available. So that then raise the question of equity in a new way, I think on a global basis and to equity in access to testing became a cornerstone of the global response. And this awareness we just talked about and how hard it is to deliver testing to fragile systems, everyone became acutely aware of that. So I think that's an important piece, is now testing is on the agenda in a way it hasn't been before and equity is a core principle. I think a few things that we've seen and realized are critical to delivering equity. One is WHO leadership. I think the WHO gets criticized sometimes for its response to emergencies, and I think WHO has been just absolutely essential and I think that the power of the WHO to deliver that message I think is critical and something we need to recognize and maintain once we move out of the pandemic. The other issue that I think has been really clear is manufacturing. Most tests for most diseases, the factories and the equipment that make the test kits and the reagents are in the global north. And that has created problems and it also made a lot of countries realize how critically they are dependent on things well outside their control politically. And so the effort that's grown over the past 12 months or a year and a half to say we need manufacturing for diagnostic tests in the global south, in Latin America, in West Africa, in South Africa, and we're building those factories. That's going to support equity, probably not in time for the pandemic when it was needed last year, but for the future for future pandemics, for tuberculosis, for tests that manufacturers in the global north don't really pay as much attention to. And that, I think, is the critical legacy of COVID, is to identify this sort of niche issue of hey, where the tests are produced is really essential for equity, especially in Africa, but across the Global South. And I think that's something we'll look back on and realize was a critical moment in this pandemic.

Garry Aslanyan [00:13:45] I can see Sikhulile you wanted to add something to this.

Sikhulile Moyo [00:13:49] I think he raised a very important point around the need to be able to produce kits and supplies within our region, and we've seen it as well, is in rolling not only to testing kits, but is also rolling out to vaccines and also several testing products that we need to increase access as well as probably innovative ways of testing. Some people tried innovative ways like food testing or different algorithms to expand testing and scale up testing. And I think that has become very, very important, I would say.

Garry Aslanyan [00:14:37] So Sikhulile, in 2021, late 2021, you and your colleagues and scientists that work with you were the ones who sounded the alarm around the Omicron variant. To me, this means that Botswana had a very good early warning detection system, supported by diagnostic capacity. Maybe you could tell our audience a little bit more about that experience and how that unfolded.

Sikhulile Moyo [00:15:10] The discovery of Omicron in Botswana was not an accident. I think it was a result of a strategic intent to increase access to detecting what is going on in the population. You need diagnostics. So testing, testing, testing, testing. So Botswana decided to make sure that there's access to testing in all its districts and increasing access, using COVID zones, where in each of the catchment area there's a PCR lab and also using the infrastructure from HIV, the sample referral system, you were able to refer samples to the next PCR lab. And we developed now a surveillance strategy that was going to be able to be built on that; that if we get a positive, we are going to sample it. And our strategy was made of so many pillars. First of all, we wanted to know what is coming into the country, surveillance of our points of entry. So if there's a new virus coming in, we were there trying to see that and sample. We were also interested to see what is happening in people who have been hospitalized, who have the first disease progression. So when there were death cases, we were also sampling those. We were also looking at generally in the population. We couldn't sequence everyone. But what is the representative way of sampling across these areas that will give us a meaningful data to estimate what is happening in the population? So this strategy allowed us to be, on a weekly basis, accumulating representative samples that cut across these different objectives. And that was very, very important. We received a lot of support from organizations like FIND and Bill & Melinda Gates Foundation and the Ministry of Health and in terms of setting up our systems and also enhancing the testing. On 11 November, we received these unique samples and they were tested in one of the labs and they noticed that; we monitor what we call cycle threshold values, it's a measure of how concentrated the virus is. So this one was very concentrated and was like, we have never seen such a concentration of viruses. And they brought it in because we were sequencing weekly, we put those samples into our batch. When we got them into our batch, we noticed that when we compared them with others, they were sitting at their own tree. When you put them into a tree of viral analysis, what we call phylogenetic analysis, we realized that these four clustered together and boom, what is this going on? When we looked at them initially as a virologist, you think there's an error, so we went back to the lab. So we could have reported this data as early as 18 November, but we went back to the lab and by the 19th we were sure that we saw exactly what we saw. And on 22 November, we notified the Ministry of Health, we made the data available, and that was a Monday, and by Tuesday we got a call from an independent group that saw our sequences and they said, "we've seen something similar". So two independent labs identifying a lineage. So for us, when we reported to the Ministry of Health, we said we've identified an unusual lineage. I still have that email and I'm framing it for future because it's changed the world. An unusual lineage. We didn't know that it's a variant. We didn't know it was a variant of concern. So when we notified the Ministry of Health in South Africa as well, then we realized that this is worth reporting to the World Health Organization. And as Bill said, WHO has played a very critical role. They formed a technical working group, and on 26 November, they classified this unusual lineage, a variant of concern, now called the Omicron. And I think for me, I was fulfilled as a scientist to report something like that, but also it was a roller coaster of emotions because the way the world reacted, our travel bans, and I think we have learned a lot over the

past two years that I think that reaction was unfortunate. Economies were damaged. Even the medicines and the vaccines that we were expecting were delayed. A lot of businesses were closed. There was a lot of lockdowns unnecessarily. So the cost implications were huge, and some of us got calls about what have you done, you scientists with your big mouth. It was the holiday season coming up and why didn't you keep quiet until we come back from Christmas? And when you look back, while we went through the rough time, I feel even more strongly that data transparency data should be shared transparently and should be used to improve public health.

Garry Aslanyan [00:20:46] Bill, beyond the developments you mentioned related to COVID-19, what are the other exciting and disruptive innovations in diagnostics that are emerging, and how could they apply to other diseases, to TB or other neglected issues, especially in low- and middle-income countries?

Bill Rodriguez [00:21:12] There are two really exciting developments that are on the near-term or medium-term horizon. One is actually sequencing. Sikhulile told a really powerful story about the identity of the Omicron and the consequences, but the commitment to sharing data and transparency and so what we're seeing under COVID is literally every country in the world now has the capacity to do sequencing of pathogens and turn that information around, share it publicly and incorporate it into a global response. And what that means for disease surveillance is potentially transformative. We will be able to track variants of every pathogen, the major viruses, HIV, TB, and to apply that not only for epidemiologic purposes to monitor diseases and something much closer to real time than we've ever been able to do before, but also potentially for clinical applications in TB drug resistance and antimicrobial resistance more generally, in HIV management. So that capacity and the cost of sequencing has come down dramatically, so that's a really powerful technology that we really had no access to in LMICs until COVID. So that's one really disruptive innovation that has come about. The second is at a technical level in what's referred to as multiplexed molecular point of care platform. What does that mean? So the first generation of these were instruments like the expert platform for tuberculosis that really made a difference in making tuberculosis diagnosis simpler, faster, less expensive. Instead of taking days or weeks to culture TB, we can now use a molecular test to identify the DNA in an hour and know that this is TB and that changes patient care dramatically. But those systems are expensive. You can just say, "is this TB"? And if the test is negative, well then what do you do? So COVID has led to the accelerated development of multiple platforms. We're tracking over 100 companies, 45 in late development, five that are already on the market, that can do multiplexed molecular testing. So that disruptive innovation, that's very likely going to transform primary health care across the world, especially in low- and middle-income countries that really have not had access to this kind of powerful technology because it was too expensive, too complicated. And we'll see those systems enter the market in 2023, 24, 25, and likely be transformative as we enter the end of this decade.

Garry Aslanyan [00:23:51] And what about you, Sikhulile, how does that play out in Botswana in terms of innovative diagnostic approaches and then future?

Sikhulile Moyo [00:24:00] It has really opened up avenues for multi-pathogen diagnosis, and a lot of these platforms that were enhanced through COVID are now open platforms that will be able to cover other pathogens, and I think this is very, very important that now we will be able to do things cheaper. And I think other than just that, we've also seen an innovative way of some digital solutions that could help us to accelerate availability of data. And if we can enhance these mobile apps to make sure data is available at a central level to enhance decision-making very fast, I think that is very, very, very important. I think that will drive quality of care. We can put these tools near patient care, I think that will really, really help.

Garry Aslanyan [00:24:57] Final question to both of you, Bill and Sikhulile, what promise does improving access to diagnostics hold for achievement of public health systems in countries, in countries such as Botswana, and obviously in other settings in low- and middle-income countries?

Bill Rodriguez [00:25:19] It's a great question. I would say we're really at the cusp of a transformation in testing as part of basic health care services on par with treatments and vaccines. And so I think we're really entering a new era where disease surveillance and clinical management are going to be much more data based, based on available tests that are widely used on a regular basis. Or in the past, a lot of what we've done has not been database systems based on best guess and empiric approaches and in mass drug administration, things that were effective for their time. But now this is a much more targeted approach that's going to make health care more efficient, more economic, and lead to better outcomes. And I don't want to overpromise what testing can do, but we've seen that potential now begin to transform public health surveillance and clinical case management in what was otherwise a pretty horrible two year period of this pandemic. That's the one legacy that I think we'll look back on and say, well, at least there was one positive impact from this virus and this pandemic on a global basis.

Sikhulile Moyo [00:26:30] I would also say that this has provided a unique opportunity that is accelerating research efforts globally and locally as well, and has highlighted other things like engaging communities and leadership in their response. We see novel platforms coming up. It means that disease diagnosis is going to be faster. And in the era of overlapping epidemics, we see an opportunity to extend cross-disciplinary research and diagnostic into integrated service delivery for HIV, for TB, for malaria. We see that these opportunities for integration and also it brings other opportunities in digital data systems because now you are generating a lot of data in a very short space of time, so you need to manage that data. So solutions for making sure that this data moves very fast, your near real time reporting to public health and alerts and emergencies and data analytics, making sure this data can provide reasonable clinical decisions, but also public health decisions is becoming a very good opportunity. And also, we see that the diagnostic industry for manufacturing diagnostics is really, really looking up to say, how can we develop these technologies here? And there are tests developed, for example, in Dakar, in Senegal, they developed their own COVID rapid tests, so I think the future is holding on to it. I mean, someone said, we should not waste a crisis. So we should utilize the opportunities that COVID has brought us to advance public health.

Garry Aslanyan [00:28:31] Thank you both for this exciting discussion and for joining our podcast.

Bill Rodriguez [00:28:38] Thanks, Garry, it was a pleasure.

Sikhulile Moyo [00:28:39] Thank you Garry.

Garry Aslanyan [00:28:42] Bill and Sikhulile hold a deep passion for their work, and this was reflected in what they shared with me. I was struck by Bill's quotes saying that pandemics don't create new problems in a society, they just reveal the existing ones. As we have heard not only in this episode, but also from so many of our guests that have spoken in the last year, this indeed is true. The COVID-19 pandemic has cast a spotlight on many failures in global health. However, the efforts from countries like Botswana and the experience of virologists like Sikhulile, gives me really great hope. This shows that it's indeed possible for countries to effectively respond during an emergency, not only safeguarding the health of their own people, but also to share their knowledge with the whole global health community. I want to commend Sikhulile and his team yet again for their skilled work in discovering the Omicron variant in Botswana. I feel there is a lot to be optimistic about with so many new diagnostic innovations brimming on the horizon. Hopefully they will reduce the gap and assist in achieving greater diagnostic equity for all.

Garry Aslanyan [00:30:01] We always welcome feedback from our listeners from around the globe. Let's hear from one of them.

Margaret McCluskey [00:30:19] In a recent GHM podcast, two women who define stellar leadership in global health made their voices heard. Garry clearly set the stage for Drs Agnes and Catherine to speak their truth, which is necessary if we are to hope that the field of global health will transition from the historic power imbalances, inherent racism and patronizing programing toward what beloved Dr Paul Farmer taught us, which has much more to do with being allies to one another.

Garry Aslanyan [00:30:53] I totally agree with you, Margaret. We must never lose sight that we are all allies in this quest for health globally. Be sure to join the Global Health Matters podcast again next month for yet another inspiring episode. Thank you for listening, subscribing and sharing the podcast with others who may be interested.

Elisabetta Dessi [00:31:17] Global Health Matters is produced by TDR, an infectious diseases research programme based at the World Health Organization. Garry Aslanyan, Lindi Van Niekerk and Maki Kitamura are the content producers. Obadiah George is the Technical Producer. This podcast was also made possible with the support of Chris Coze, Elisabetta Dessi, Iza Suder-Dayao, Noreen O'Gallagher and Chembe Collaborative. The goal of Global Health Matters is to provide a forum for sharing perspectives on key issues affecting global health research. Send us your comments and suggestions by email or voice message to TDRpod@who.int, and be sure to download and Subscribe wherever you get your podcasts. Thank you for listening.